

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No: 10/791,447
Applicant: Janzen Lo et al.
Filed: March 2, 2004
Title: SURGICAL INSTRUMENT FOR IMPLANTS
TC/A.U.: 3733
Examiner: Mary C. Hoffman
Confirmation No.: 3444
Notice of Appeal Filed: July 16, 2008
Docket No.: BBM-147US

SUPPLEMENTAL APPEAL BRIEF UNDER 37 C.F.R. § 41.37

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Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

S I R :

This Supplemental Appeal Brief is filed in reply to the September 26, 2008 Notification of Non-Compliant Appeal Brief. Appellants respectfully submit that this Supplemental Appeal Brief addresses the issues raised in the Notification and is fully compliant.

Appellants hereby request consideration and reversal of the Final Rejection dated May 16, 2008 of claims 1-5, 20 and 21.

This Brief is presented in the format required by 37 C.F.R. § 41.37, in order to facilitate review by the Board. In compliance with 37 C.F.R. § 41.37(a)(1), this Brief is being filed within the time allowed for response to the action from which the Appeal was taken or within two months from the date of the Notice of Appeal, whichever is later.

The necessary fees were paid in conjunction with the filing of the original Appeal Brief on September 15, 2008.

I. REAL PARTY IN INTEREST

The real Party In Interest in this matter is Aesculap II, Inc. by virtue of an assignment recorded on May 11, 2007, at Reel/Frame 019286/0034.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences related to the subject matter of this Appeal.

III. STATUS OF CLAIMS

Claims 1 and 3-21 are pending, with claims 6-19 withdrawn, and claim 2 is canceled. Claims 1, 3-5, 20 and 21 stand rejected. Claims 1 and 3-5, 20 and 21 are the subject of this appeal.

IV. STATUS OF AMENDMENTS

No amendments have been filed subsequent to the final rejection.

V. SUMMARY OF THE CLAIMED SUBJECT MATTER

As set forth in the pending independent apparatus claim 1, the presently claimed invention relates to an implant insertion device 60 as shown generally in Figs. 14-20. As explained in the specification at page 14, lines 27-29, the purpose of the implant insertion device 60 is to guide a bone implant 10, 10', 10'', 10''' to an implantation site in a patient's body and deposit the bone implant 10, 10', 10'', 10''' in the implantation site.

Referring to the specification beginning at page 14, line 18, the implant insertion device 60 includes a handle 62, an insertion rod 64 that is attached to the handle 62, and an implant gripper 66 attached to the insertion rod 64. The implant gripper 66 includes a gripping surface 68. Referring to Fig. 15, a movable pin 70 and a fixed pin 72 are located on and extend from the gripping surface 68. Also included is a pin actuator 74 for moving the movable pin 70 between an extended position and a retracted position relative to the gripping surface 68.

As explained at beginning at page 15, line 11, the gripping surface 68 may be in the form of a v-shape to accommodate and effectively abut the flat sidewall portions 20, 20', 20'', 20''' of the bone implant 10, 10', 10'', 10''', as shown in Figs. 15 and 16. Preferably, the movable pin 70 and the fixed pin 72 make an angle ϕ 76 of about 30 degrees. This angle ϕ 76 is in accordance with the angle θ 30 of about 30 degrees of the first embodiment of the implant 10 so that the movable pin 70 and the fixed pin 72 fit flushly inside the insertion pin holes 22 and 26.

As further explained beginning at page 16, line 1, the pin driving shaft 82 is sized to accommodate a pin driver 84 that can be attached to the movable pin 70 in order to drive the movable pin 70 into a insertion pin hole 26, 26', 26'', 26'''. Activating the pin actuator 74 causes the pin driver 84 to drive the movable pin 70 into the insertion pin hole 26, 26', 26'', 26'''. As shown in Figures 19 and 20, the movable pin 70 is movable between a retracted position (Figure 19) and an extended position (Figure 20).

As set forth in the pending independent apparatus claim 20, the presently claimed invention relates to an implant insertion device 60 as shown

generally in Figs. 14-20. As explained in the specification at page 14, lines 27-29, the purpose of the implant insertion device 60 is to guide a bone implant 10, 10', 10", 10"" to an implantation site in a patient's body and deposit the bone implant 10, 10', 10", 10"" in the implantation site.

Referring to the specification beginning at page 14, line 18, the implant insertion device 60 includes a handle 62, an insertion rod 64 that is attached to the handle 62, and an implant gripper 66 attached to the insertion rod 64. The implant gripper 66 includes a gripping surface 68. Referring to Fig. 15, the longitudinal axis of the insertion rod 64 intersects the gripping surface 68. Also with reference to Fig. 15, a movable pin 70 and a fixed pin 72 are located on and extend from the gripping surface 68. Preferably, the movable pin 70 and the fixed pin 72 make an angle ϕ 76 of about 30 degrees. This angle ϕ 76 is in accordance with the angle θ 30 of about 30 degrees of the first embodiment of the implant 10 so that the movable pin 70 and the fixed pin 72 fit flushly inside the insertion pin holes 22 and 26. Also included is a pin actuator 74 for moving the movable pin 70 between an extended position and a retracted position relative to the gripping surface 68 (see Figs. 19 and 20).

As set forth in the pending independent apparatus claim 21, the presently claimed invention relates to an implant insertion device 60 as shown generally in Figs. 14-20. As explained in the specification at page 14, lines 27-29, the purpose of the implant insertion device 60 is to guide a bone implant 10, 10', 10", 10"" to an implantation site in a patient's body and deposit the bone implant 10, 10', 10", 10"" in the implantation site.

Referring to the specification beginning at page 14, line 18, the implant insertion device 60 includes a handle 62, an insertion rod 64 that is attached to the handle 62, and an implant gripper 66 attached to the insertion rod 64. The implant gripper 66 includes a gripping surface 68. Referring to Fig. 15, the longitudinal axis of the insertion rod 64 intersects the gripping surface 68. Also with reference to Fig. 15, a movable pin 70 and a fixed pin 72 are located on and extend from the gripping surface 68. Also included is a pin actuator 74 for moving the movable pin 70 between an extended position and a retracted position relative to the gripping surface 68 (see Figs. 19 and 20).

As explained at beginning at page 15, line 11, the gripping surface 68 may be in the form of a v-shape to accommodate and effectively abut the flat sidewall portions 20, 20', 20", 20''' of the bone implant 10, 10', 10", 10'''', as shown in Figs. 15 and 16. Preferably, the movable pin 70 and the fixed pin 72 make an angle ϕ 76 of about 30 degrees. This angle ϕ 76 is in accordance with the angle θ 30 of about 30 degrees of the first embodiment of the implant 10 so that the movable pin 70 and the fixed pin 72 fit flushly inside the insertion pin holes 22 and 26.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Whether claims 1, 3-5, 20 and 21 are unpatentable under 35 U.S.C. § 103(a) over Michelson in view of McCue et al.

VII. ARGUMENT

A. § 103(a) Rejection

Claims 1, 3-5, 20 and 21 were rejected under 35 U.S.C. § 103(a) as unpatentable over Michelson in view of McCue et al.

It is respectfully submitted, however, that none of the cited prior art references teach the subject matter recited in independent claims 1, 20 and 21 or their respective dependent claims. Significantly, none of the cited art, either alone or in combination, teach an implant insertion device including first and second pins that are offset on the gripping surface and extend in a non-parallel manner.

A tenet which is highly significant to the prosecution of the present application is set forth in MPEP Section 2143.03. That is, to "establish prima facie obviousness of a claimed invention, all claim limitations must be taught or suggested by the prior art." In re Rozka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Additionally, as set forth by the Supreme Court in KSR Int'l Co. v. Teleflex, Inc., No. 04-1350 (U.S. Apr. 30, 2007), it is necessary to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the prior art elements in the manner claimed.

Independent claim 1 recites "[a]n implant insertion device comprising: an insertion rod having a longitudinal axis; and an implant gripper attached to said insertion rod, said implant gripper including: a v-shaped gripping surface intersecting the longitudinal axis of the insertion rod; a first pin extending from and fixed relative to said v-shaped gripping surface; and a second pin extending through and movable relative to said v-shaped gripping surface between a first position wherein the second pin extends from the v-shaped gripping surface a distance x and a second position wherein the second pin extends a distance less than x from the v-shaped gripping surface, wherein said first pin and said second pin are offset on said v-shaped gripping surface and extend in a non-parallel manner."

Similarly, independent claim 20 recites "[a]n implant insertion device comprising: an insertion rod having a longitudinal axis; and an implant gripper extending from said insertion rod, said implant gripper including: an implant gripping surface intersecting the longitudinal axis of the insertion rod; a first pin extending from and fixed relative to said implant gripping surface; and a second pin extending through and movable relative to said implant gripping surface, said second pin being substantially aligned with said longitudinal axis of said insertion rod and non-parallel to said first pin."

Independent claim 21 recites "[a]n implant insertion device comprising: a handle having a gripping surface; an insertion rod extending from said handle, said insertion rod defining a longitudinal axis; an implant gripper extending from said insertion rod, said implant gripper including: an implant gripping surface intersecting the longitudinal axis of the insertion rod; a first pin extending from and fixed relative to said implant gripping surface; and a second pin extending through and movable relative to said implant gripping surface, said second pin being substantially aligned with said longitudinal axis of said insertion rod and non-parallel to said first pin; and an actuator positioned proximal to said handle for moving the second pin relative to said v-shaped gripping surface."

The Office Action acknowledges that Michelson fails to disclose the first and second pins that are offset by an angle of approximately 30 degrees. Without any specific support, the Office Action cites McCue et al. as disclosing first and second pins offset by an angle of approximately 30 degrees. Applicants respectfully submit that McCue et al. does not teach such and instead teaches a series of pins which are all parallel to one another.

Figures 4 and 6 of McCue et al. show three bolts 114 and 136 extending from the flat connecting end of the handle. The bolts 114 and 136 are illustrated as extending parallel to one another. There is no teaching or suggestion anywhere in McCue et al. that these bolts 114, 136 are anything other than parallel to one another. Furthermore, the operation of the device as taught in McCue et al. requires the bolts to be parallel to one another. As explained at column 3, line 56 through column 4, line 14, that the bolts 136 are inserted axially into the holes 128. Since both bolts 136 are fixed, they must be parallel to one another to be able to

move axially and engage the spaced apart holes 128. Bolt 114 is then extended axially to lock the position of the bolts 136 after they have been moved sideways to the area of reduced opening.

The cited references, alone or in any reasonable combination, fail to teach or suggest first and second pins extending from a gripping surface in a non-parallel manner. The Office Action acknowledges on page 4, in response to applicants' arguments, that the references do not teach a non-parallel configuration. Instead, the Office Action states, without any support therefore, that it would have been obvious to one having ordinary skill in the art at the time the invention was made to rearrange parallel pins into a non-parallel configuration, "since it has been held that rearranging parts of an invention involves only routine skill in the art."

The Office Action provides no support for this assertion, but instead utilizes impermissible hindsight to argue that since individual components were found in the prior art, the claimed invention is obvious. The Office Action does not provide a reason that would have prompted a person of ordinary skill in the relevant field to combine the prior art elements in the manner claimed as required under KSR Int'l Co. v. Teleflex, Inc.

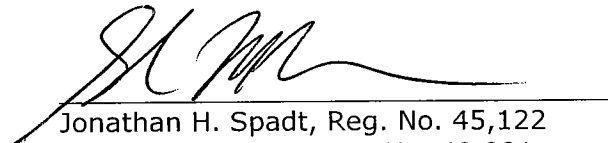
It is respectfully submitted that independent claims 1, 20 and 21 are in condition for allowance. Claims 3-5 all ultimately depend from claim 1 and are therefore allowable for, inter alia, the reasons set forth above. Additionally, withdrawn claims 6-19 all ultimately depend from independent claim 1 and should be reinstated and allowed as dependent upon an allowable generic claim.

VIII. CONCLUSION

In view of the arguments set forth above, all pending claims are patentable over the cited references. The rejection of all of the pending claims of record should therefore be reversed with instructions to issue a Notice of Allowability. Moreover, Appellants request reconsideration and allowance of claims 6-19, which are withdrawn to a nonelected species, upon the allowance of the generic claim. Such actions are respectfully requested.

Respectfully Submitted,

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Enclosures: Claims Appendix
Evidence Appendix
Related Proceedings Appendix

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The Director is hereby authorized to charge or credit Deposit Account No. **18-0350** for any additional fees, or any underpayment or credit for overpayment in connection herewith.

CLAIMS APPENDIX

1. An implant insertion device comprising:

an insertion rod having a longitudinal axis; and

an implant gripper attached to said insertion rod, said implant gripper

including:

a v-shaped gripping surface intersecting the longitudinal axis of the insertion rod;

a first pin extending from and fixed relative to said v-shaped gripping surface;

and

a second pin extending through and movable relative to said v-shaped gripping surface between a first position wherein the second pin extends from the v-shaped gripping surface a distance x and a second position wherein the second pin extends a distance less than x from the v-shaped gripping surface,

wherein said first pin and said second pin are offset on said v-shaped gripping surface and extend in a non-parallel manner.

2. (Canceled)

3. The insertion device of claim 1, wherein said first pin and said second pin are offset on said gripping surface by an angle of approximately 30 degrees.

4. The insertion device of claim 1, wherein said first pin and said second pin are smooth.

5. The insertion device of claim 1, wherein said implant gripper is removable from said insertion rod.

6. A method of engaging an implant with an implant insertion device according to claim 1, comprising the steps of:

(a) retracting the second pin relative to the gripping surface of the implant insertion device;

(b) positioning the implant adjacent to the gripping surface such that the first pin extending from the gripping surface extends into an insertion pin hole of the implant; and

(c) extending the second pin relative to the gripping surface such that the second pin extends into a second insertion pin hole of the implant, thereby effectively reversibly locking the implant onto said device.

7. The method of claim 6 further comprising the step of

(a) retracting the second pin of the implant gripper from the insertion pin hole of the implant; and

(b) moving the gripping surface away from the implant such that the first pin is removed from the second insertion pin hole of the implant and the implant insertion device is disengaged from the implant device.

8. A method of insertion of an implant with an implant insertion device according to claim 1, comprising the steps of:

(a) attaching the implant to the implant insertion device by retracting the second pin relative to the gripping surface of the implant insertion device; positioning the implant adjacent to the gripping surface such that the first pin extending from the gripping surface extends into an insertion pin hole of the implant, and extending the second pin relative to the gripping surface such that the second pin extends into a second insertion pin hole of the implant;

(b) inserting said implant in a spinal column; and

(c) detaching said implant from said implant insertion device by retracting said second pin from said second insertion pin hole of said implant, and detaching said first pin of said implant gripper from said insertion pin hole of the implant.

9. An implant insertion assembly comprising:

an implant insertion device according to claim 1; and

an implant comprising an outer sidewall which defines one or more insertion pin holes configured to receive the first and second pins.

10. The assembly according to claim 9, wherein said insertion pin holes include a counter bore cut.

11. The assembly according to claim 9, wherein the implant outer sidewall includes at least two flat sidewall portions and first and second insertion pin holes are defined along the respective flat sidewall portions.

12. The assembly according to claim 9, wherein said implant includes a superior end face and an inferior end face and one or both of said superior end face and said inferior end face include a plurality of radial cuts.

13. The assembly according to claim 12, wherein said plurality of radial cuts are tiered.

14. The assembly according to claim 9, wherein said implant includes a superior end face and an inferior end face and one or both of said superior end face and said inferior end face include a plurality of concentric cuts.

15. The assembly according to claim 14, wherein said plurality of concentric cuts are tiered.

16. The assembly according to claim 9, wherein said implant includes a superior end face and an inferior end face and one or both of said superior end face and said inferior end face include a plurality of concentric cuts and a plurality of radial cuts.

17. The assembly according to claim 9, wherein said implant defines a hollow core.

18. The assembly according to claim 9, wherein said implant is a biocompatible material.

19. The assembly according to claim 9, wherein said implant insertion device is a biocompatible material.

20. An implant insertion device comprising:

an insertion rod having a longitudinal axis; and

an implant gripper extending from said insertion rod, said implant gripper including:

an implant gripping surface intersecting the longitudinal axis of the insertion rod;

a first pin extending from and fixed relative to said implant gripping surface; and

a second pin extending through and movable relative to said implant gripping surface, said second pin being substantially aligned with said longitudinal axis of said insertion rod and non-parallel to said first pin.

21. An implant insertion device comprising:

a handle having a gripping surface;

an insertion rod extending from said handle, said insertion rod defining a longitudinal axis;

an implant gripper extending from said insertion rod, said implant gripper including:

an implant gripping surface intersecting the longitudinal axis of the insertion rod;

a first pin extending from and fixed relative to said implant gripping surface; and

a second pin extending through and movable relative to said implant gripping surface, said second pin being substantially aligned with said longitudinal axis of said insertion rod and non-parallel to said first pin; and an actuator positioned proximal to said handle for moving the second pin relative to said v-shaped gripping surface.

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EVIDENCE APPENDIX

None

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RELATED PROCEEDINGS APPENDIX

None